

REMARKS

Claims 15-16, 22-26 and 30-39 are currently pending. Claim 40, which was previously cancelled but erroneously included in prior communications, has been cancelled once again (without prejudice) to clarify the record. The claims have been amended to overcome the new ground of rejection set forth in the Decision on Appeal, to remove various grammatical and/or typographical inconsistencies, as well as to define other patentable aspects of the present invention. Applicants respectfully request favorable consideration of the present application as amended in view of the following remarks.

I. New Rejection

In the Decision on Appeal mailed November 15, 2005 ("Decision"), claims 15-16, 22-26 and 30-40 were rejected under 35 USC 112, 2nd paragraph, as failing to particularly point out and distinctly claim the subject the appellants regard as the invention. In response, Appellants have amended claim 15 to eliminate the inconsistencies referenced on page 8 of the Decision on Appeal. More specifically, clause (b) was amended to clarify that neuro-muscular responses are monitored (via electromyography) from *muscles* coupled to a spinal nerve of interest, which is addresses the rejection basis set forth at lines 6-12 of page 8 of the Decision. Clause (c) of claim 15 was amended to remove the rejected claim language (set forth at lines 12-23 of page 8 of the Decision). Claim 15, as now amended, is believed to particularly point out and distinctly claim the subject Appellants regard as the invention. Appellants respectfully request that the rejection of the claims under 35 USC 112, 2nd paragraph, be withdrawn.

II. Prior Rejection

In an effort to facilitate the reopened prosecution, the Appellants would like to address amended claim 15 as it relates to the rejections in the Final Office Action, namely alleged obviousness under 35 USC 103(a) over Raymond '331, Raymond '153, Raymond '154, and/or Hadzic in view of Feler.

Claim 15, as currently amended, reads as follows:

15. A method for assessing the proximity of a spinal nerve relative to a distal end of at least one probe or surgical tool being introduced towards a patient's spine, said spine having a generally anterior region, a generally posterior region opposite from said generally anterior region, and generally lateral regions extending between said generally anterior region and said generally posterior region, comprising:

(a) emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced generally perpendicularly towards a generally lateral region of the patient's spine;

(b) electromyographically monitoring muscles coupled to said spinal nerve to determine if a predetermined neuro-muscular response is elicited by the stimulus signal;

(c) determining the relative distance between said spinal nerve and said distal end of said probe or surgical tool based on the intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response; and

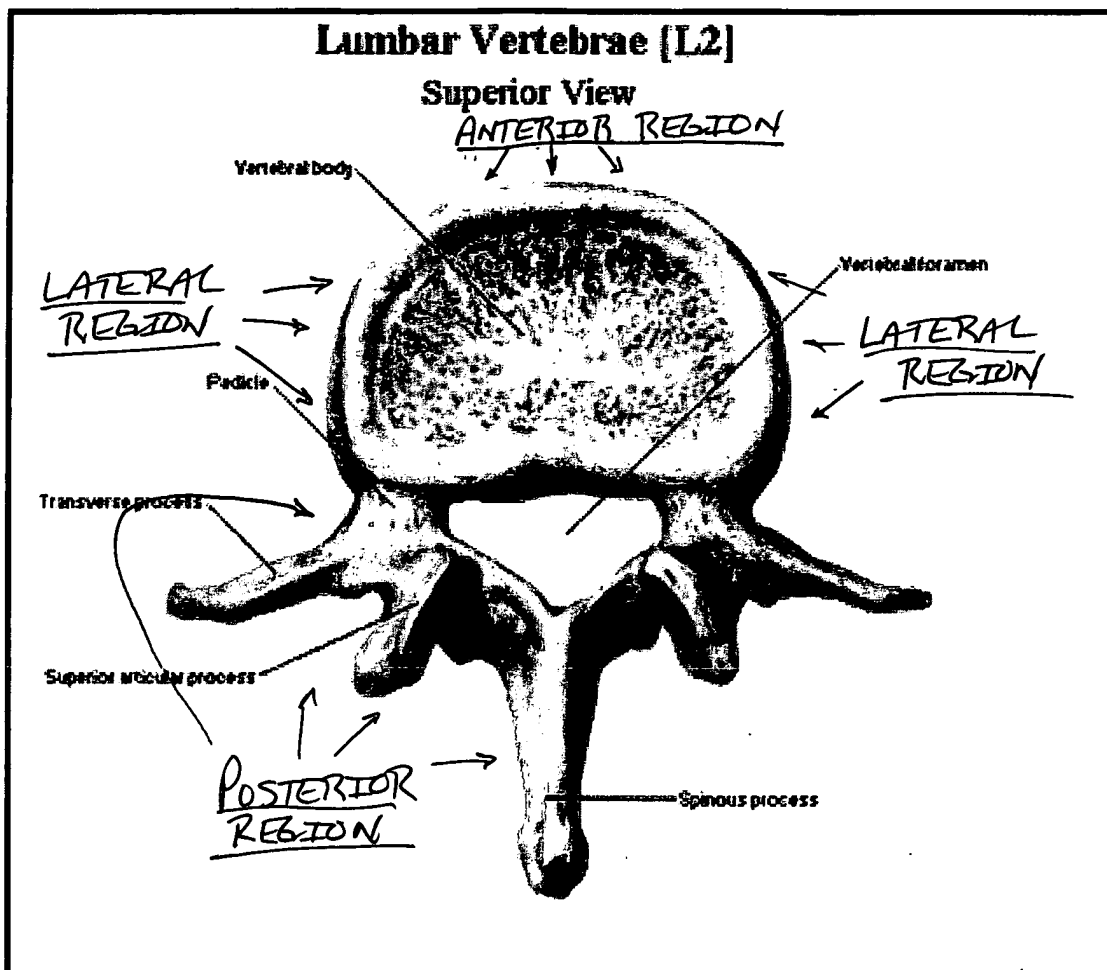
(d) communicating to an operator said intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. In determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Appellants respectfully submit that the references relied upon to support the Final Rejections fail to establish a *prima facie* case of obviousness regarding amended claim 15. First, none of the references appear to teach or disclose the feature of “emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced *generally perpendicularly towards a generally lateral region of the patient’s spine.*”

The preamble of claim 15 was amended to clear up the apparent miscommunication about the approach of the present invention by defining the basic physical regions of a patient’s spine: (1) a generally anterior region; (2) a generally posterior region opposite from the generally anterior region; and (3) generally lateral regions extending between the generally anterior region

and the generally posterior region.” With reference to the figure below, the generally Anterior Region is located at the top of the figure, and comprises the region forming the front or anterior portion of the vertebral body. The Posterior Region is located at the bottom of the figure, and comprises the region rearward or behind the vertebral body (including the pedicle, transverse process, articular processes, and spinous process). The Lateral Regions extend between the Anterior Region and the Posterior Region on either side of the vertebral body.



With reference to FIGS. 1 and 4 in the subject application, it is clear that the approach of the present invention involves introducing a probe or surgical tool 20, 22 in a manner that is generally perpendicular to the lateral region of the patient's spine.

Contrary to the Board's comments in footnote 2 on page 4 of the Decision, the Raymond '153, Raymond '154, and Hadzic references all appear to be silent with respect to this feature as now set forth in Claim 15. Indeed, each of these references merely illustrates advancing an electrified needle towards a nerve located in the arm of a patient, and none of these references make any mention or teaching about spinal nerves, much less approaching the patient's spine in a manner that is generally perpendicular to a lateral region thereof.

This defect is not cured by Feler. In footnote 2 on page 4 of the Decision, the Board asserted that "Feler appears to suggest, if not actually teach, introduction of a probe towards a patient's spine from a generally lateral direction at, for example, column 3, lines 38 through 42, column 4, lines 59 through 61, and column 7, line 65, through column 8, line 1." While Feler does use the word "lateral" in a few instances, a close reading would make clear that Feler does not teach approaching a spinal nerve in a manner that is generally perpendicular to a lateral region of a patient's spine. Indeed, as described in column 7, line 65 through column 8, line 1, the surgeon "causes stimulation lead 114 to move in a transverse direction relative to the *dorsal* [that is, posterior] column of the patient." As explained above, the present invention approaches the lateral region of the patient's spine, as opposed to the posterior region as in Feler.

Moreover, even if one were to assume, *arguendo*, that Feler discloses or suggests the introduction of a probe towards the patient's spine from a generally lateral direction (which Appellants do not agree with), the Feler reference actually teaches *away* from the present

invention. As such, there's no reason why someone of ordinary skill in the art would be motivated to combine in the manner proposed in the Final Office Action and Decision.

More specifically, the Feler reference discloses the use of somatic sensory evoked potentials (SSEP), as opposed to electromyography (EMG). The somatic sensory system transmits sensory information from regions of the body to the central nervous system (i.e. brain and spinal cord). Sensory information may include mechanical sensations (e.g. displacement, pressure, touch, muscle tension), thermal sensations, and pain. SSEP involves applying a stimulation signal to a particular region of the body to evoke a potential in the central nervous system. Depending upon the time lapse between the application of the stimulation signal and the corresponding SSEP, a surgeon can assess whether the neural pathways between the particular region of the body and the central nervous system are functioning normally or whether they have been impaired (such as may be due to injury or the application of intentional nerve blocking agents for anesthesia or to treat chronic pain). As explained at column 4, lines 39-47 of Feler (and shown in FIG. 3), the resulting SSEP activity is preferably monitored via electrodes 116 located on the skull of the patient via electroencephalography (EEG). Importantly, noise interference from muscle activity is to be avoided (column 4, line 47; column 5, lines 58-60; column 8, lines 41-45) to ensure accurate results of the SSEP activity.

Claim 15, on the other hand, specifically recites the use of EMG: "electromyographically monitoring muscles coupled to said spinal nerve to determine if a predetermined neuro-muscular response is elicited by the stimulus signal." Not only is EMG fundamentally different from SSEP, it is based on the specific evil to be avoided per Feler (muscle activity). Because Feler

teaches away from the use of EMG in this manner, Appellants respectfully submit that one of ordinary skill in the art would *not* have been motivated to combine Feler with the other references in the manner proposed in the Final Office Action and Decision.

In addition to the foregoing distinctions, none of the cited references appear to disclose the claimed feature: “communicating to an operator said intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response.” At most, some of the references involving EMG communicate the *responses* of the nerves to the stimulation signals (e.g., Raymond ‘153 at column 4, lines 26-29). However, that is a significant distinction from communicating the *intensity level* of the stimulus signal required to elicit the responses. Communicating the intensity level of the stimulus signal required to elicit the responses is advantageous, among other reasons, because it greatly simplifies the procedure for a user. In particular, the user need not review and assess the actual waveforms of the resulting neuro-muscular (EMG) responses to appreciate the proximity between the probe or surgical tool and the particular spinal nerve. Rather, the user can simply and quickly appreciate (e.g. via visual and/or audible information) the proximity between the spinal nerve and the probe or surgical tool with reference to the intensity level required to elicit the responses. As such, the user does not need to be specially trained to read or assess neuro-muscular waveforms (such as is the case with neuropsychologists, who are traditionally required to read and decipher such waveforms). This allows the process of assessing nerve proximity during surgery to move out of the hands of neuropsychologists and into those of the actual surgeons. This advantageously eliminates the difficulties of scheduling time of both the neuropsychologist and the surgeon (whose schedules may conflict and thereby cause a patient to wait for a suitable time and lengthen their period of

suffering). This also advantageously eliminates the extra cost associated with having a neurophysiologist participate in the surgery, in that the nerve proximity determination may now be accomplished by the surgeon.

Based on the foregoing distinctions between claim 15 (as amended) and the prior art of record, Appellants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as now claimed) based on the cited references. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 16, 22-26 and 30-39, being dependant upon and further limiting independent claim 15, should be allowed for the reason set forth in support of the allowability of claim 15, as well as the additional limitations they contain.

III. Conclusion

Favorable consideration and allowance of the claims are respectfully requested. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
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